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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,841	08/13/2001	Peter Francis Leadlay	0380-P02381U	6738

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SUITE 720
1601 MARKET STREET
PHILADELPHIA, PA 19103-2307

EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/05/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,841

Applicant(s)

LEADLAY ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18,20-22 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18,20-22 and 25-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Application Status

1. The instant Office action is a supplemental Office action to the previous Office action (Paper No. 6 mailed on March 20, 2002). The instant action is a duplicate of Paper No. 6 except for two items: (1) the "Period for Reply" marked on PTO-326 that has been changed to **ONE MONTH** instead of the 3 months as previously cited and (2) on page 2 of the Office action, the claim numbers in Group I were incorrectly noted and should be "Group I, Claims 1-6, drawn to polyketides" as is obvious for the description of the Group.
2. Prior to examination, Applicants filed an amendment on October 29, 2001 (Paper No. 5). Said amendment cancelled Claims 19, 23, and 24, amended Claims 11-14, 16-18, 20, 22, and 25 and added new Claims 26-30. Thus, Claims 1-18, 20-22, and 25-30 are pending in the instant application.

Restriction of Inventions

3. Restriction is required under 35 U.S.C. § 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 C.F.R. § 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn to polyketides.

Group II, claim(s) 7-9, 28 and 30, drawn to generic methods of making formula 1 compounds.

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Group III, claim(s) 10-18, 20-22, 25, and 29, drawn to DNA systems for producing polyketides.

Group IV, claim(s) 26 and 27, drawn to PKS enzymes.

4. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

“A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involved at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed inventions, considered as a whole, makes over the prior art.” (see M.P.E.P. § 1893.03(d))

In the instant case, the *technical* feature linking all the pending claims is a polyketide that has an acetate incorporated as a starter unit (see Claims 1 and 10 and 27). However, the technical feature is **not a special technical feature** because the polyketide, as claimed, does not contribute over the prior art as evidenced in the International Search Report (PCT/ISA/210) and International Preliminary Examination Report (PCT/IPER/409). Lacking a special technical feature, the pending claims are restricted according to their substance as different products (Groups I, III, and IV) and their different categories (Group II – method claims).

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Restriction of Species

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In Group I, the species are as follows:

15-norerythromycin A

15-norerythromycin B

formula 1: numerous species at various R positions

In Group II, the species are as follows:

methods of making formula 1: numerous species at various R positions

In Group IV, the species are as follows:

PKS enzymes for making formula 1: numerous species at various R positions

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added

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after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Election

6. A telephone call was made to Patrick Hagan on March 11, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion


7. A complete response to the instant Office action must contain an election of invention to be examined and, if necessary, an election of species.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

KMK
March 28, 2002